

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Charles E. ROGLER et al.

Serial No.: TBA (Continuation of Serial No. 09/344,189)

Art Unit: 1632

Filed: Concurrently herewith

Examiner: P. Paras, Jr.

For: **CHRONIC HEPATITIS VIRUS INFECTION AND CLONAL HEPATO-CELLULAR CARCINOMA IN MOUSE REPOPULATED LIVERS**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

March 19, 2004

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☒ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months

prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449, PTO-892, or form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.

☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

☒ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 09/344,189, filed June 24, 1999; and

Serial No. 09/156,892, filed September 18, 1998.

Applicant Identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP § 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) _____ are set forth as follows: An English language abstract is included for each of the documents. The documents further include chemical formulas for which no additional translation is believed to be required.
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

☒ 5. Other information being provided for the examiner's consideration follows:

An International Search Report, dated February 17, 2000, which issued during the prosecution of International Application No. PCT/US99/21838 which corresponds to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

[INSERT SERIAL NO. AND FILING DATE]

Early and favorable consideration is earnestly solicited.

Respectfully submitted,



Mitchell Bernstein, Ph.D.
Registration No. 46,550
Agent for Applicant(s)

DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 753-6237 (fax)

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

(REV. 7-80)

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3368/1D888-US1

SERIAL NO: 09/344,189

APPLICANTS: Charles E. ROGLER et al.

FILING DATE: June 24, 1999

U.S. PATENT DOCUMENTS

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>NAME</u>	<u>CLASS SUBCLASS</u>	<u>FILING DATE</u>
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FOREIGN PATENT DOCUMENTS

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>COUNTRY</u>	<u>CLASS SUBCLASS</u>	<u>TRANSLATION YES NO</u>
/M.W./	1. WO 94/02601	Feb. 3, 1994	EPO	C12N 15/00	X

OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)*****EXAMINER
INITIALS**

EXAMINER: /Michael Wilson/ (03/26/2008) DATE CONSIDERED: 03/26/2008

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 0342/1D888US1
 APPLICANT: Charles E. ROGLER
 FILING DATE: 06/24/99

SERIAL NO: 09/344,189

U.S. PATENT DOCUMENTS

*EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

*EXAMINER INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
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OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

*EXAMINER
INITIALS

/M.W./


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1. Chisari, F.V. *et al.* (1995) *Annu. Rev. Immunol.* 13:29-60
 2. Chisari, F.V. (1996) *Curr Topics Microbiol Immunol* 206:150-173
 3. Guidotti, L.G. *et al.* (1994) *Proc. Natl. Acad. Sci. USA* 91:3764-3768
 4. Guidotti, L. G. *et al.* (1996) *Immunity* 4:25-36
 5. Gupta, S. *et al.* (1996) *Prog Liv Dis* 14:199-222
 6. Sandgren, E.P. *et al.* (1991) *Cell* 66:245-256
 7. Rhim, J.A. *et al.* (1994) *Science* 263:1149-1152
 8. Rhim, J.A., *et al.* (1995) *Proc. Natl. Acad. Sci. USA* 92:4942-4946
 9. Roggendorf, M. *et al.* (1995) *Intervirolgy* 38:100-112
 10. Korba, B.E. *et al.* (1989). *J Virol* 63:1360-70

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 0342/1D888US1
APPLICANT: Charles E. ROGLER
FILING DATE: 06/24/99

SERIAL NO: 09/344,189

- /M.W./
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11. Tennant, B.C. *et al.* (1994) in *The Liver. Biology and Pathobiology*, eds. Arias, I.M., *et al.* (Raven Press, New York) pp 1455-1469
 12. Shinkai, Y. *et al.* (1992) *Cell* 68:855-867
 13. Overturf, K. *et al.* (1996) *Nature Genetics* 12:266-273
 14. Grompe, M. *et al.* (1993) *Genes and Development* 7:2298-2307
 15. Overturf, K. *et al.* (1997) *Am. J. Path.* 151:1273-1280
 16. Marie-Jeanne, T. *et al.* (1997) *Hepatology* 25:884-888
 17. Petersen, J. *et al.* (Sept. 1997) Abstract No. 041, Molecular Biology of Hepatitis B Viruses, Institut Pasteur
 18. Petersen, J. *et al.* (1998) *Proc. Natl. Acad. Sci. USA* 95:310-315
 19. Petersen, J. *et al.* (1997) *Hepatology* 26(4), pt. 2, 225A, Abstract # 387

EXAMINER: /Michael Wilson/ (03/26/2008)

DATE CONSIDERED: 03/26/2008

***EXAMINER:**

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(DSO Form PTO 17)

Substitute for form 1449A/B/PTO <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 0;">(Use as many sheets as necessary)</p>			Complete if Known	
Application Number	Not Yet Assigned			
Filing Date	Concurrently Herewith			
First Named Inventor	Charles E. Rogler			
Art Unit	1632			
Examiner Name	Not Yet Assigned			
Attorney Docket Number	03368/100D888-US3			

Sheet	1	of	1
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U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	CA	Laconi, E. et al. (1998) American Journal of Pathology, Vol. 153, pp. 319-327		
	CB	Janeway Jr., C. et al. (1997) Immunobiology, 3d, pp. 317-319		
	CC	Overturf, K., et al. (1996) Nature Genetics, Vol. 12, pp. 265-272		
	CD	Mercer, D., et al. (2001) Nature Medicine, Vol. 7, pp. 927-932		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

(W:033 68100d	/Michael Wilson/ (03/26/2008)	Date Considered	03/26/2008
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Notice of References Cited

Application/Control No.

09/344,189

Examiner

Peter Paras, Jr.

Applicant(s)/Patent Under
Reexamination
ROGLER, CHARLES E.

Art Unit

1632

Page 1 of 1

U.S. PATENT DOCUMENTS

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							APS	OTHER
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NON-PATENT DOCUMENTS

*		DOCUMENT (Including Author, Title Date, Source, and Pertinent Pages)	DOCUMENT SOURCE **	
			APS	OTHER
<input type="checkbox"/>	U	Kuby et al, 1994, Immunology, 2nd edition, Freeman Press, page 26.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	V		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	W		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	X		<input type="checkbox"/>	<input type="checkbox"/>

A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)

**APS encompasses any electronic search i.e. text, image, and Commercial Databases.

U.S. Patent and Trademark Office

PTO-892 (Rev. 03-98)

Notice of References Cited

Part of Paper No. 5

Notice of References Cited

Application/Control No.

09/344,189

Applicant(s)/Patent Under

Reexamination
ROGLER, CHARLES E.

Examiner

Peter Paras

Art Unit

1632

Page 1 of 2

U.S. PATENT DOCUMENTS

*	Document Number		Date MM-YYYY	Name	Classification	
	Country	Code-Number-Kind Code				
A	US	6,004,207	09-1997	Vierling	800	9
B	US	5,583,272	06-1994	Alt et al.	600	2
C	US	5,860,860	03-1997	Kay et al.	424	93.21
D	US	-				
E	US	-				
F	US	-				
G	US	-				
H	US	-				
I	US	-				
J	US	-				
K	US	-				
L	US	-				
M	US	-				

FOREIGN PATENT DOCUMENTS

*	Document Number		Date MM-YYYY	Country	Name	Classification	
	Country	Code-Number-Kind Code					
N	-	-					
O	-	-					
P	-	-					
Q	-	-					
R	-	-					
S	-	-					
T	-	-					

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages					
U	WS Robinson, Fundamental Virology, 2nd Ed., "Hepadnaviridae and Their Replication," 1991, Chap. 38, pp. 989-1021.					
V	FB Hollinger et al., Fields Virology, "Hepatitis A Virus," 3rd. Ed., Chap. 24, pp. 705 and 751-752.					
W	RH Purcell, Fields Virology, "Hepatitis E Virus," 3rd. Ed., Chap. 80, pp. 2831-2836.					
X	SC Burngardner et al., Immunological Reviews, "Unusual patterns of alloimmunity evoked by allogeneic liver parenchymal cells," 2000, Vol. 174, pp. 260-279.					

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a))
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited

Application/Control No.

09/344,189

Applicant(s)/Patent Under

Reexamination

ROGLER, CHARLES E.

Examiner

Peter Paras

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1632

Page 2 of 2

U.S. PATENT DOCUMENTS

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A	US-			
B	US-			
C	US-			
D	US-			
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G	US-			
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J	US-			
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M	US-			

FOREIGN PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N	-				
O	-				
P	-				
Q	-				
R	-				
S	-				
T	-				

NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	M Houghton, Fields Virology, 3rd Ed, "Hepatitis C Viruses," Chap 32, pp. 1035-1036
V	
W	
X	

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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.